# IncobotulinumtoxinA for Provoked Vestibulodynia With Overactive Pelvic Floor Muscle Dysfunction

NCT07486830

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| **Status** | RECRUITING |
| **Phase** | Phase 2 |
| **Sponsor** | Center for Vulvovaginal Disorders |
| **Enrollment** | 54 participants |

## Key Eligibility Criteria

### Inclusion (12)

- Female, 18 years or older.
- Willing to provide a written informed consent prior to any study related procedures.
- Premenopausal.
- Have vulvodynia with provoked vestibulodynia with overactive pelvic floor muscle dysfunction for at least 3 months duration and for no more than 15 years.
- Have provoked pain at the posterior vestibule on a cotton swab test, with pain at positions 4, 6 and 8 o'clock (must be bilateral pain) at the Baseline Visit.

... and 7 more (see full listing online)

### Exclusion (25)

- Have provoked pain on a cotton swab test at the anterior vestibule (anywhere between 9 and 3 o'clock or more anteriorly) at the Baseline Visit.
- Able to tolerate the 6th (diameter 1 1D4 inches) dilator size (i.e. agree to the next successive dilator size to be tested for pain response) at the Baseline Visit with a pain score less than 5 (i.e. blue dilator).
- Genitourinary or gastrointestinal conditions/history which, according to the investigator's judgment may interfere with treatment or impact outcome assessment, including but not limited to:
- Skin disease at the vestibule such as lichen sclerosus, lichen planus, vaginal or vulvar atrophy, desquamative inflammatory vaginitis, allergic vulvitis, etc.
- Severe endometriosis (as defined as requiring regular medications other than hormonal contraceptives and NSAIDS to manage the endometriosis symptoms).

... and 20 more (see full listing online)

## Locations (2 total)

Center for VulvoVaginal Disorders, Washington D.C., District of Columbia, United States
Centers for Vulvovaginal Disorders, NY, New York, New York, United States